



Medtronic Xomed, Inc.  
Martin Sargent  
Regulatory Affairs Manager  
6743 Southpoint Dr. North  
Jacksonville, Florida 32216

June 8, 2021

Re: K010666

Trade/Device Name: Xps 3000 System With Reciprocating Adapter And Suction Cannulae  
Regulation Number: 21 CFR 878.5040  
Regulation Name: Suction lipoplasty system  
Regulatory Class: Class II  
Product Code: QPB

Dear Martin Sargent:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated May 7, 2001. Specifically, FDA is updating this SE Letter because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Cindy Chowdhury, OHT4: Office of Surgical and Infection Control Devices, 240-402-6647, [Cindy.Chowdhury@fda.hhs.gov](mailto:Cindy.Chowdhury@fda.hhs.gov).

Sincerely,

**Cindy Chowdhury -S**

Cindy Chowdhury, Ph.D., M.B.A.  
Assistant Director  
DHT4B: Division of Infection Control  
and Plastic Surgery Devices  
OHT4: Office of Surgical  
and Infection Control Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY - 7 2001

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Martin Sargent  
Regulatory Affairs Manager  
Medtronic Xomed  
6743 Southpoint Drive North  
Jacksonville, Florida 32216

Re: K010666  
Trade/Device Name: XPS 3000 System  
Regulation Number: 878.5040  
Regulatory Class: II  
Product Code: MUU  
Dated: March 5, 2001  
Received: March 6, 2001

Dear Mr. Sargent:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative  
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): K010666  
Device Name: XPS 3000 System  
Indications for Use:

The XPS 3000 system with reciprocating adapter and suction cannula is intended for the removal of soft tissue and fluid during general surgical procedures including suction lipoplasty for aesthetic body contouring.

*[Signature]*  
(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices

510(k) Number K010666

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use *[Signature]*  
(Per 21 CFR 801.109)

Or

Over-the-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)

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510(k) Summary

**1.0 Date Prepared**

March 5, 2001

**2.0 Submitter (Contact)**

Martin D. Sargent  
Regulatory Affairs Manager  
Medtronic Xomed  
Jacksonville, FL  
(904) 279-7586

**3.0 Device Name**

Proprietary Name: XPS 3000 System with reciprocating adapter and suction cannulae  
Common Name(s): Electrical surgical shavers, electrical debridors, drill handpieces and cutting blades, burs, rasps, reciprocating handpieces, and cannulae  
Classification Name(s): Suction lipoplasty system and accessories;  
Surgical instrument, AC powered motors, accessories and attachments

**4.0 Device Classification**

Classification Name: Suction lipoplasty system  
Procode 79MFF, Class II 21 CFR § 878.5040

Classification Name: Suction lipoplasty accessories  
Procode 79MUU Class II 21 CFR § 878.5040

Classification Name: Surgical instrument, AC powered motors, accessories and attachments  
Procode 79GEY Class I 21 CFR § 878.4820

**5.0 Device Description**

The XPS 3000 system consists of a power control console, footswitches, connection cables, and assorted handpieces to drive various burs, blades, drills, rasps, and reciprocating cannulae.

K010666

#### **6.0 Indications for Use**

The XPS 3000 with reciprocating adapter and suction cannula is intended for the removal of soft tissue and fluid during general surgical procedures including suction lipoplasty for aesthetic body contouring.

#### **7.0 Substantial Equivalence**

The proposed XPS 3000 system is substantially equivalent in operating principle, technology, overall design, function, materials, and intended use to the XPS / Powersculpt System as described in K992855.